510(k) Summary

General Provisions	Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern, PA 19355 610-651-5000 610-651-5003 Alina Stubbs July 08, 2013 2529252
Subject Device	Trade Name: Common/Usual Name: Classification Name:	HeartSpan™ Steerable Introducer Kit Steerable Introducer Kit Catheter Introducer (21 CFR §870.1340)
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	HeartSpan™ Steerable Introducer Kit Catheter Introducer (21 CFR §870.1340) K122431 Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern, PA 19355 (formerly operating as Thomas Medical Products, Inc.)
Classification	Class II 21 CFR §870.1340 FDA Product Code: DYB Review Panel: Cardiovascular	
Intended Use	The HeartSpan™ Steerable Introducer Kit is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	

SEP 17 2013

Device Description	The HeartSpan™ Steerable Introducer set consists of a dilator, guide wire, and steerable sheath, which are designed for catheter introduction into the cardiac anatomy. The device is provided sterile (ethylene oxide) and intended for single use only. It is for use in hospitals or healthcare facilities. The steerable introducer contains a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The introducer handle includes a rotating knob to enable clockwise and counterclockwise tip deflection $\geq$180° with a radius of 10 – 56 mm (measured at 180° deflection) . The steerable introducer also includes distal holes to facilitate aspiration and minimize cavitation, a radiopaque tip marker to improve fluoroscopic visualization, an atraumatic soft tip, and a lubricious coating on the inner and outer surfaces. The dilator is designed to conform to the inner diameter of the sheath, and has a tapered tip. The materials of construction are primarily polymers with the exception of stainless steel braid reinforcement and deflection wires in the introducer shaft that are completely encapsulated in the sheath wall and do not contact the patient or bodily fluids.

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Comparison to Predicate

Summary of the technological characteristics of the device compared to the predicate devices:

Technical Characteristics	**Predicate Device (K122431)**	**Modified Device (K132164)**
Hemostasis valve provided	Yes	Yes
Dilator to Guide wire Compatibility	up to 0.038"	up to 0.038"
Guide wire Design / Dimensions	Standard Non-Coated 0.038" x 135cm	Super-Stiff with PTFE 0.032" x 180cm
Compatibility with Standard Transseptal Needle	Yes	Yes
Length	74 cm	74 cm
French size	8.6F	8.6F
Bi-Directional Curving	Yes ≥180° in both directions	Yes ≥180° in both directions
One-Handed Operation of Curving Mechanism	Yes	Yes
Wire braid reinforcement completely encapsulated	Yes	Yes
Radiopaque tip or marker	Yes	Yes
Soft Atraumatic Tip	Yes	Yes
Side port for infusion and contrast injection	Yes	Yes

Safety & Performance Tests

The HeartSpan™ Steerable Introducer Kit has been thoroughly tested through verification of product specifications and user requirements. The following quality assurance measures were applied during the development of the HeartSpan™ Steerable Introducer Kit:

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Performance Testing (Verification) including but not limited to:
  - Tip articulation
  - Leak resistance
  - Kink resistance
  - Length
  - Inner/Outer diameter
  - Curve radius
  - Marker band location
  - Tip/tube detachment force
  - Side hole diameter and location
- Sterilization validation (ethylene oxide)
- Biocompatibility Testing (Verification)

The results of the testing demonstrated that the modified HeartSpan™ Steerable Introducer Kit meets the predetermined acceptance criteria applicable to safety and efficacy of the device.

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International Standards	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for this device. Performance testing of the modified HeartSpan™ Steerable Introducer Kit was conducted based on the risk analysis and based on the requirements of the following international standards: • ANSI/AAMI/ISO 10993-3:2003 Biological Evaluation of Medical Devices – Part 3: Tests of Genotoxicity, Carcinogenicity, and Reproductive Toxicity • ANSI/AAMI/ISO 10993-4:2002 Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood • ANSI/AAMI/ISO 10993-5:1999 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity • ANSI/AAMI/ISO 10993-7: 2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals • ANSI/AAMI/ISO 10993-10: 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization • ANSI/AAMI/ISO 10993-11: 2006, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity • ISO 11070:1998 Sterile Single-Use Intravascular Catheter Introducers – Annex B • ANSI/AAMI/ISO 11135-1:2007 Sterilization of Health Care Products – Ethylene oxide – Part 1: Requirements for Development, Validation and Routine Control of Sterilization Process for Medical Devices • ISTA P2A (2011) - Packaged-Products 150 lb (68kg) or Less
Summary of Substantial Equivalence	Merit Medical Systems, Inc. considers the HeartSpan™ Steerable Introducer Kits to be substantially equivalent to the currently marketed predicate device (HeartSpan™ Steerable Introducer Kit K122431). This assessment is based upon analysis of similar technological characteristics, bench testing, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 17, 2013

Ms. Alina Stubbs
Regulatory Affairs Specialist II
Merit Medical Systems, Inc.
65 Great Valley Parkway
Malvern, PA 19355

Re: K132164
Trade Name: HeartSpan™ Steerable Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II
Product Code: DYB
Dated: August 16, 2013
Received: August 19, 2013

Dear Ms. Stubbs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Section 4 Indications for Use Statement

510(k) Number (if known): K132164

Device Name: HeartSpan™ Steerable Introducer Kit

Indications for Use:

The HeartSpan™ Steerable Introducer Kit is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Prescription Use X AND/OR Over-The-Counter-Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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